Data Evaluation Report on the effects of BAS 800 H metabolite M08 on earthworms

PMRA Submission Number: 2008-0431 **MRID#: 47560307**

PMRA# for DER: 1681997 **PMRA# for original study: 1664707**

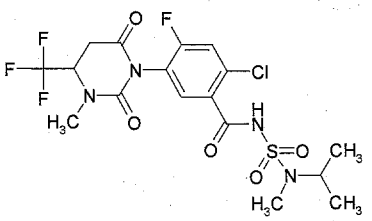
Data requirement

PMRA Data Code:	9.2.3.1
EPA DP Barcode:	349851
OECD Data Point:	IIA 8.9.1
EPA Guideline:	n/a
OPPTS Guideline:	850.6200

Test material: **BAS 800 H metabolite M08** **Purity:** 95.1%

Common name:	M800H08
IUPAC:	N-[2-chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluoromethyl)tetrahydro-1(2H)-pyrimidynal)benzoyl]-N-isopropyl-N-methylsulfamide
CAS name:	n/a
CAS No.:	n/a
Synonyms:	Reg.No. 4773881

Structural formula:



Primary Reviewer: Janine Glaser (1009) **Date:** 2008-Dec-16
HC-PMRA-EAD

Secondary Reviewers: Anita Pease **Date:** 2009-Jun-09
United States-EPA-OPP-EFED-ERB4

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Farzad Jahromi **Date:** 2009-Feb-2
Australia-DEWHA-CAS

PMRA Company Code	BAZ
PMRA Active Code	SFF
PMRA Use Site Category	13, 14
EPA PC Code	118203

CITATION: Lührs U. 2008. Acute toxicity (14 days) of Reg. No. 4773881 (metabolite of BAS 800 H, M800H08) to the earthworm *Eisenia fetida* in artificial soil. 2008-Aug-5. BASF-2008/1036410; MRID-47560307; PMRA-1664707.

EXECUTIVE SUMMARY

In an acute toxicity laboratory study, adult earthworms of the species *Eisenia fetida* Savigny (Annelida: Oligochaeta), were exposed to M800H08 (metabolite of BAS 800 H, 95.1% purity). The test item was mixed into artificial soil at rates of 31.25, 62.5, 125, 250, 500 and 1000 mg/kg dry soil. For the control treatment, the soil was left untreated. The worms were introduced on top of the soil. Four replicates were prepared for the treatment groups, each containing 10 worms. Assessment of mortality and behaviour (e.g. lack of movement, rigidity) was made 7 and 14 days after application. Mean body weight per test container was determined on day 0 and 14 days after application.

After 14 days of exposure, no mortality was observed in the control and the test item concentrations. The biomass development was not statistically significantly inhibited at any test item concentration (Dunnett's test $\alpha = 0.05$). No other particular behavioral or morphological changes were observed. The 14d LC_{50} of was >1000 mg/kg dry soil, the 14d LOEC was >1000 mg/kg dry soil, the 14d NOEC was 1000 mg/kg dry soil.

This study is classified as **ACCEPTABLE/ FULLY RELIABLE**. The results are suitable for use in regulatory risk assessment.

Results Synopsis

Test item:	M800H08
Test organism:	adult *Eisenia fetida*
14d LR50:	>1000 mg/kg dry soil
Probit slope:	n/a
14d LOEC:	>1000 mg/kg dry soil
14d NOEC:	1000 mg/kg dry soil
Endpoints affected:	none

I. MATERIALS AND METHODS

Guideline: OECD 207 (1984), ISO 1268-1 (1993)
GLP: yes (certified laboratory)
Testing facility: Institut für Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany
Dates of work: 2008-Jun-25 to 2008-Aug-4
Deviations: None

A. Test substance

Name: Reg.No. 4773881
Code: M800H08

Type: metabolite of BAS 800 H
Description: beige solid
Batch No.: L80-46
Purity: 95.1%
Expiry date: 2010 Mar 01
Dosing vehicle: 20g fine quartz sand

Table: Physical and chemical properties of test substance

Parameter	Value
Water solubility	31.71 mg/l at 25°C (estimated)
Vapour pressure	not determined
UV absorption	not determined
pK_a	not determined
log K_{ow}	-0.51±1.01 (neutral pH) -2.51±1.01 (acidic pH)
Stability under test conditions	considered stable

B. Toxic reference

2-Chloroacetamide. The effects of the reference item were evaluated in a separate study at 0, 15.8, 20.5, 26.6, 34.6, and 45.0 mg/kg dry soil for 14 days.

C. Test organisms

Species: *Eisenia fetida*
Common name: earthworms
Age: 10-month-old adults with clitellum
Weight: 304-596 mg
Source: in-house culture
Acclimatization: 1 day in artificial soil under test conditions

D. Test substrate

Type: Artificial soil prepared according to OECD 207
Sphagnum-peat: 10%
Kaolin clay: 20%
$CaCO_3$ (pH6): 0.6%
Fine quartz sand: 69.4%
Max WHC: 58% of dry weight

E. Design of biological test

14-d exposure in treated artificial soil prepared according to OECD 207. Different concentrations of the test item were each mixed homogeneously into 500g dry soil, which was then used to fill 1L glass vessels after which the earthworms were introduced on top of the soil. 7 treatment groups (nominal concentrations of 0, 31.25, 62.5, 125, 250, 500 and 1000 mg M800H08/kg dry

soil); 4 replicates/treatment group with 10 worms each.

F. Observation and measurements

Assessment of mortality and behaviour (e.g. lack of movement, rigidity) was made 7 and 14 days after application. Mean body weight per test container was determined on day 0 and 14 days after application.

II. RESULTS

A. Test conditions

Soil pH:	start pH 6.3-6.5; end pH 6.0-6.1 (slight decline)
Water content:	27.9-32.0% (48.1-55.2% of max WHC) (no change over time)
Test temperature:	18.0-22.0°C
Photoperiod:	continuous illumination
Light intensity:	410-670 lux

B. Verification of test concentrations

Not required.

C. Biological findings

After 14 days of exposure, no mortality was observed in the control and the test item concentrations. On average, the worms gained weight (3.0-11.9%) over the 14 days in all treatments. The biomass development was not statistically significantly inhibited in the whole concentration range (Dunnett-test $\alpha = 0.05$), and there was no dose-response relationship observed. No other particular behavioral or morphological changes were observed. The results are summarized in the following table.

Table: Effects M800H08 on mortality of *Eisenia fetida* after 14 days

mg/kg dry soil	Mortality (%)	Weight change (%)
0	0	5.0
31.25	0	3.0
62.5	0	4.6
125	0	7.9
250	0	8.9
500	0	11.9
1000	0	9.2

The Regulatory Authority did not verify the statistical analyses since there was no mortality at any dose and no dose-response relationship in biomass development.

D. Test with toxic reference substance

For 2-chloroacetamide, the 14d LC_{50} of was 27.0 mg/kg dry soil, the 14d LOEC was 20.5 mg/kg

dry soil, the 14d NOEC was 15.8 mg/kg dry soil. This is within the expected range.

E. Validity criteria

The validity criterion of 14d control mortality ≤10% was fulfilled. The validity criterion for 14d control mean loss of biomass ≤20% was fulfilled.

F. Biological endpoints derived

From the results presented above, the following biological endpoints were derived from the study author and verified by the Regulatory Authority:

14d LR50:	>1000 mg/kg dry soil
Probit slope:	n/a
14d LOEC:	>1000 mg/kg dry soil
14d NOEC:	1000 mg/kg dry soil
Endpoints affected:	none

III. STUDY DEFICIENCIES

None.

V. CONCLUSIONS

This study is classified as **ACCEPTABLE/ FULLY RELIABLE**. The study appears to have been well conducted and reported. The results are suitable for use in regulatory risk assessment. The 14d LC_{50} of was >1000 mg/kg dry soil, the 14d LOEC was >1000 mg/kg dry soil, the 14d NOEC was 1000 mg/kg dry soil.